

Appl. No. : 09/574,819
Filed : May 19, 2000

REMARKS

Claims 27-32 are pending in this application.

A. Compliance with 35 USC 102

The Patent Office rejected Claim 27 under 35 USC 102(a) as being anticipated by Storm et al., Nature 368:639 (14 April 1994), which describes a sequence encoding a protein comprising SEQ ID NO: 24 but does not describe chondrogenic activity. According to MPEP 715, a Declaration under 37 CFR 1.131 can be used to overcome a 35 USC 102(a) rejection. Applicant filed a Declaration of Prior Invention in the United States To Overcome Cited Publication Under 37 CRF § 1.131 (signed July 2004) to swear behind Storm et al. at a date prior to 14 April 1994. The Patent Office questioned its effectiveness to overcome the Storm reference. As described below, attached is a copy of Supplemental Declaration of Prior Invention in the United States To Overcome Cited Publication Under 37 CRF § 1.131 to swear behind Storm et al. at a date prior to 14 April 1994.

B. Compliance with 35 USC 103

The Patent Office rejected the claims under 35 USC 103(a) as being unpatentable over Storm et al., Nature 368:639 (14 April 1994), and Neidhardt PCTEP93/00350, published 19 August 1993. Under the statute, a patent may not be obtained if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made. Neidhardt is admitted not to describe a sequence encoding a protein comprising SEQ ID NO: 24, only expression vectors, host cells, and processes for the production of proteins. The Supplemental Rule 131 Declaration establishes prior invention prior to 14 April 1994. At the time the invention was made, Neidhardt's description of only expression vectors, host cells, and processes for the production of proteins could not have rendered the subject matter as a whole obvious because a sequence encoding a protein comprising SEQ ID NO: 24 was unknown. The secondary reference does not fill in the gap left by the antedating of the primary reference, thus the rejection cannot prevail.

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C. Supplemental Declaration Under 37 CFR § 1.131

The issue is whether the Supplemental Rule 131 Declaration is sufficient to overcome the 102(a) rejection *indirectly* under 37 CFR 1.131. The rule according to MPEP 715.03 “Genus Claim” is that proof of prior completion of a species different from the species of the reference will be sufficient to overcome a reference indirectly if the species shown in the reference would have been obvious in view of the species shown to have been made by the applicant. *Alternatively*, if the applicant cannot show possession of the species of the reference in this manner, the applicant may be able to antedate the reference indirectly by, for example, showing prior completion of *one or more species* which put him in possession of the claimed genus prior to the reference’s date. The test is whether the species completed by applicant prior to the reference date provided an adequate basis for inferring that the invention has generic applicability. The MPEP goes on to say that it is not necessary for the evidence to show that the applicant viewed his invention as encompassing more than the species actually made. The test is whether the facts set out in the showing are such as would persuade one skilled in the art that the applicant possessed so much of the invention as is shown in the reference. *Accord* MPEP 715.02. Here, proof of prior completion of a species different from the species of the reference (mouse) is sufficient to overcome a reference *indirectly*. Here, the *alternative* is met because the Applicant is able to antedate the reference indirectly by showing prior completion of *one* (per Rule 131 Declaration signed July 2004 and Rule 131 Declaration signed August 1999: bovine) *or more* (per Supplemental Rule 131 Declaration: *Xenopus*) *species* which put him in possession of the claimed genus (defined by the amino sequence motif of SEQ ID NO: 24) prior to the reference’s date of 14 April 1994. Here, the facts set out in the showing are such as would persuade one skilled in the art that the Applicant possessed so much of the invention (the claimed genus defined by the amino acid sequence motif of SEQ ID NO: 24) as is shown in the Storm et al. reference.

Referring to Supplemental Rule 131 Declaration ¶ 3, genomic DNA was isolated from *Xenopus*. Referring to Supplemental Rule 131 Declaration ¶ 3, the genomic DNA was used as the template for amplification of sequences in a PCR protocol that used primers corresponding to

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highly conserved motifs in the mature region of the BMPs. Referring to Supplemental Rule 131 Declaration ¶ 4, amplified DNA fragments were subcloned according to standard procedures. Referring to Supplemental Rule 131 Declaration ¶¶ 5-7, the inserts from various isolates were sequenced by standard dideoxy chain termination protocols. Referring to Supplemental Rule 131 Declaration ¶ 8, alignments of the products obtained by PCR indicated that CDMP family members from *Xenopus* and zebrafish that was cloned using the same approach (“Like Logan’s #21 24 AA, 1 Different”) shared a common amino acid sequence motif except at one position. Referring to Supplemental Rule 131 Declaration ¶ 9, which incorporates by reference Rule 131 Declaration signed July 2004 and Rule 131 Declaration signed August 1999, alignments of the products obtained by PCR indicated that CDMP-2 (which is GDF-6 of Storm et al.) family members from *Xenopus* and bovine shared the common amino acid sequence motif at every position. Referring to Supplemental Rule 131 Declaration ¶ 10, it can be seen that the Applicant completed one or more species which put him in possession of the claimed genus (defined by the amino sequence motif of SEQ ID NO: 24) prior to the reference of Storm et al.

In sum, proof of prior completion of a species different from the species of the reference (mouse) is sufficient to overcome Storm et al. *indirectly*. The Applicant is able to antedate the reference indirectly by showing prior completion of *one* (per Rule 131 Declaration signed July 2004 and Rule 131 Declaration signed August 1999: bovine) *or more* (per Supplemental Rule 131 Declaration: *Xenopus*) *species* which put him in possession of the claimed genus (defined by the amino sequence motif of SEQ ID NO: 24) prior to the reference’s date of 14 April 1994. The facts set out in the showing are such as would persuade one skilled in the art that the Applicant possessed so much of the invention (the claimed genus defined by the amino acid sequence motif of SEQ ID NO: 24) commensurate with the extent of the invention as claimed is shown in the Storm et al. reference.

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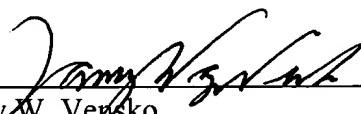
CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: 
Nancy W. Vensko
Registration No. 36,298
Attorney of Record
Customer No. 45,311
(805) 547-5585

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